Developing a Laboratory Accreditation Program For HAVA

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National Voluntary Laboratory Accreditation Program

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Why Laboratory Accreditation (and Conformity Assessment)?

- So you don’t have to worry.
  - Confidence - it has been done right
  - Competence - get the right answer
  - Equivalence - get the same answer
  - Independence - nothing else is going on
  - Appropriateness - fit for purpose

What is NVLAP?

- A process for accreditation of testing and calibration laboratories
- Established in the U.S. Code of Federal Regulations (Title 15, Part 285) in 1976
- Administered by NIST
- Linked to NIST research units
- Based on international (ISO/IEC) standards
- Available to any qualifying laboratory (public - private)
- Fee supported
- Signatory to several international MRAs
- 800+ labs in the system today

Developing a Program

- start with NIST Handbook 150
- NVLAP seeks input from all sectors of the community including laboratories, developers, vendors, standards writers, regulators, customers, certifiers, the public
- NVLAP receives request for new program
- NVLAP publishes the request for a new program in the Federal Register
- expert advice is sought
- input is needed both now and later

Accreditation to ISO 17025

- Review of documents: Quality Manual, Procedures Manual, Instructions, Records, ...
- On-site assessment by a team of peer technical experts (who have had ISO 17025 training)
- Participation in proficiency testing
- Evaluation of the above by NVLAP team
- feedback to the laboratory
- corrective action by the laboratory

ISO 17025 addresses - Management requirements

- Organization
- Quality system
- Document control
- Review of requests, tenders and contracts
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Service to the client
- Complaints

ISO 17025 addresses - Management requirements - cont'd

- Control of nonconforming testing and/or calibration work
- Corrective action
- Preventive action
- Control of records
- Internal audits
- Management reviews

ISO 17025 addresses - Technical requirements

- General
- Personnel
- Accommodation and environmental conditions
- Test and calibration methods and method validation
- Equipment
- Measurement traceability
- Sampling

ISO 17025 addresses - Technical requirements - cont'd

- Handling of test and calibration items
- Assuring the quality of test and calibration results
- Reporting the results

Typical On-site Visit - conducted every other year

- Entry meeting with lab management
- Review documentation including quality system, records, competency reviews,..
- Examine facilities, hardware, software,..
- Staff interviews
- Competency quiz and demonstrations
- Conduct proficiency testing
- Exit meeting
  - On-Site Assessment Report given to lab
  - Responses required are discussed

Quality System includes

- quality manual
- policies, objectives, commitments
- procedures - management and technical
- instructions - management and technical
- records - management and technical
- roles and responsibilities

- quality manual sent to NVLAP with application for assessor to review
- discussed during on-site assessment

Proficiency Testing

- determination of competency - both applied (proficiency testing) and intellectual (quizzes)
- an integral part of the accreditation process - customized for field
- a means of periodically checking laboratory performance and ability
- required for initial and/or continuing accreditation
- conducted during on-site assessment visit and/or between visits

Developing a Program - 1/5

- identify testing laboratory community (how many, will they apply for accreditation)
- identify laboratory user community
- identify standards development organizations for hardware, software, and systems
- identify test methods and standards
- Identify who will improve and interpret test methods and standards
- identify product certification and validation programs

Developing a Program - 2/5

- identify regulatory bodies
- identify other stakeholders
- identify sources of technical expertise and assistance
- Identify sources of training for labs and vendors
- identify level of "traffic" - how many labs and how much work is there
- select the "units" of the Scope of Accreditation

Developing a Program - 3/5

- establish specific technical requirements
- establish laboratory staff qualifications and certifications
- Set priorities - what is most important
- components of a laboratory: equipment, facilities, environment, software, ...
- establish accreditation process sequence
- develop the assessment techniques for on-sites, quizzes, demonstrations, etc.

Developing a Program - 4/5

- set time needed for on-site assessments
- design proficiency testing programs
- set criteria, seek, and select peer technical expert assessors
- train assessors to use ISO 17025
- set on-site team size and "skill set"
- create NVLAP program-specific checklist(s)
- NVLAP Program Handbook 150-xx for the new program detailing specific technical requirements

Developing a Program - 5/5

- establish evaluation criteria for granting of accreditation
- hold public workshops
- establish fee schedule (estimate $11k for first year, $4k for second year)
- contents of NVLAP application package
- publish Federal Register announcement
- time window for accepting initial applications - after that, no restrictions